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California Department of General Services
Real Estate Services Division
Professional services branch, Environmental services section
Attn – Valerie Namba, Senior Environmental Planner
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This letter is in response to the publication of the Draft Environmental Impact Report (DEIR) for the use of PEX and the related codes published by the California Building Standards Commission.

My comment is in regard to the Project Description section of the DEIR. This section refers to several proposed changes to section 604 of the state plumbing code. My comment is that this listing is incomplete. In addition to the proposed changes to section 604, section 613.1 should also be updated.

The current verbiage of 613.1 reads "*Dialysis water feedlines shall be PVC, glass, or Stainless Steel and sized to provide minimum velocity of 1.5 ft per second.*"

This section (as worded today) contradicts the proposed changes to section 604 allowing PEX. It is also redundant to 613.7 which states that Dialysis Water systems must meet relevant AAMI (Association for the Advancement of Medical Instrumentation) standards -- these AAMI standards already include requirements on dialysis water feedline materials (including PEX), configuration, and design; some of which contradict the outdated text in 613.1. Additionally, section 613.1 (as worded today) violates the Code of Federal Regulations 21-CFR-808 which states that "*no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act [emphasis added].*"

Proposed changes are to either eliminate section 613-1 altogether or to amend it to state *"Dialysis water feedlines shall be constructed to meet relevant AAMI and/or FDA guidelines"*.

Gambro has petitioned OSHPD several times over the last 5 years to change section 613.1. However, OSHPD has denied the petitions due (in part) to the current wording of 604.1 prohibiting PEX. Clearly any proposed change to section 604.1 should also apply to 613.1.

Please contact me if you have any questions or need any further supporting information

Best Regards

A handwritten signature in black ink, appearing to read "Robert J. Chambers". The signature is fluid and cursive, with the first name "Robert" and last name "Chambers" clearly distinguishable.

Bob Chambers
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